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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/779,455 | 02/09/2001 | Tarun K. Dhar | 056859/0115 | 6699 |

22428 7590 09/26/2003

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[REDACTED] EXAMINER

NGUYEN, BAO THUY L

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1641

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/779,455 | DHAR ET AL. |
| Examiner | Art Unit | |
| Bao-Thuy L. Nguyen | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6, 8-20 and 44-46 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 8-20 and 44-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Applicant's amendment filed July 14, 2003 has been received. Claims 7-21 have been cancelled. Claims 22-43 have been withdrawn. Claims 44-46 have been added. Currently, Claims 1-6, 8-20 and 44-46 are pending.
2. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.
3. The text of those US codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 1-6, 8-20 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the description of the absorbent material. The relationship between the absorbent and the reaction membrane and bottom support layer is unclear since it has not been defined. The claim is also silent with respect to the function of the absorbent. It appears that a kit comprising different components, one of which is an absorbent body is being claimed. If this is the case, the claim should be amended for clarity.

Claims 4 and 5 imply a contact between the absorbent body and the reaction membrane, however, the relationship between the different components of the device and the absorbent body is unclear as stated above.

Claim 10 contains typographic errors. Correction is required.

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Claims 11 and 45 recite a loose area on the reaction membrane which is unclear. What is this loose area? And how is it "loose"?

Claims 13 and 46 are confusing since it appears to recite that in addition to the electron-rich blocking protein recited in claim 1, the reaction membrane is further blocked with another type of blocking protein. Such a device does not have support in the specification as originally filed.

The recitation of "the unused binding sites on nitrocellulose" in claim 13 lacks antecedent support.

Claim 18, "the separately provided absorbent body" lacks antecedent support.

Claim 20, "wherein" should be deleted for clarity.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13 and 46 recite that in addition to the electron-rich blocking protein recited in claim 1, the reaction membrane is further blocked with another type of blocking protein such as casein, BSA and gelatin. Such a device does not have support in the

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specification as originally filed. The specification calls for the application of either electron rich blocking proteins such as p-hydroxy-phenylpropionic acid-casein conjugates and p-hydroxy-phenylpropionic acid-gelatin conjugates, or the application of the more common blocking proteins known in the art such as casein and BSA. The specification does not teach a device in which unused binding sites are blocked using both types of blocking protein together.

Claim Rejections - 35 USC § 103

7. Claims 1-12, 14-21 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (US 5,807,522) in view of Lin et al (US 6,265,176) and Bhattacharya et al (Journal of Immunological Methods. 227:31-39. 1999).

Brown discloses a substrate formed of a water-impermeable backing having thereon a porous membrane. The porous membrane is applied to the backing by a variety of methods including heat-seal stamping, laminating or via adhesives (column 12). Ligands such as antigen or antibody is applied in a spotted array onto the membrane (columns 6 and 15).

Brown differs from the instant invention in failing to teach a body of absorbent material provided separately nor does Brown teach the use of electron-rich blocking proteins.

Lin, however, discloses analytical test kits and method comprising test cards or strips of an inert plastic carrier having a flat, non-absorbent surface having antigen or antibody spotted thereon. The spots on the card may be more than one reagent for testing for multiple unknowns. During use, the spot is washed and blotted dry using absorbent blotting papers. Lin teaches test kits comprising the carrier and blotting papers.

Bhattacharya discloses the use of electron-rich blocking proteins such as p-hydroxy-phenylpropionic acid-casein conjugates and p-hydroxy-phenylpropionic acid-gelatin conjugates

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as blocking agents. Bhattacharya teaches that such blocking agents provide the advantage of an increase in sensitivity and increased the detection limits in ELIZA.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the blotting papers taught by Lin in the test system and kit of Brown because such blotting papers are well known in the art. The use such blotting papers provides the advantage of a shorter assay time because test cartridges may be blotted dry instead of air dry thus reducing the time needed and optimizing assay conditions. It also would have been obvious to replace the blocking agents taught by Brown with those of Bhattacharya for the advantages stated above.

8. Claims 1, 3-15, 18-21 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearns et al (US 5,573,919) in view of Lin et al (US 6,265,176) and Bhattacharya et al.

Kearns discloses an assay for detecting analyte comprising absorbent contained in a casing made of plastic. The absorbent membrane has a porosity such that it can retain particles having a size of about 0.1 micron to 10 microns. See column 2, line 41 through column 2, line 11; and column 3, lines 17 through column 4, line 17. Kearns teaches coating the surface with BSA to prevent non-specific binding. See column 6, lines 8-20 and 44-57.

Kearns differs from the instant invention in failing to teach a body of absorbent material provided separately and the use of electron-rich blocking agents.

See the discussion of Lin and Bhattacharya above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the blotting papers taught by Lin in the test system and kit of Kearns because such blotting papers are well known in the art. The use such blotting papers provides the advantage of a shorter assay time because test cartridges may be blotted dry

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instead of air dry thus reducing the time needed and optimizing assay conditions. It also would have been obvious to replace the BSA blocking agent taught by Kerns with the electron-rich blocking agents of Bhattacharya for the advantages stated above.

Conclusion

9. No argument was submitted with the amendment, and because Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. The indicated allowability of claim 14 is withdrawn in view of the newly discovered reference(s) to electron-rich blocking proteins. Rejections based on the newly cited reference(s) are discussed above.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy Nguyen
Primary Examiner
23 July 2003